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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,935	06/08/2001	Daniel Pinto	13294-002001	1394

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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/877,935		PINTO ET AL.	
	Examiner		Art Unit	
	Celine X Qian Ph.D.		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-12,32,33 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-12,33,35, 36 and 39-43 is/are rejected.
- 7) ☒ Claim(s) 3-6,8,37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-7, 8-13, 32, 33, 35-43 are pending in the application.

This Office Action is in response to the Amendment filed on 10/21/04.

Response to Amendment

The objection to claim 35 has been withdrawn in light of Applicant's amendment of the claims

The rejection of claims 9, 32 and 35 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

Claims 1, 2, 8-12, 33 and newly added claims 42 and 43 are rejected under 35 U.S.C. 112 1st paragraph is maintained for reason set forth of the record mailed on and further discussed below.

Claims 3-6, 8 and newly added claim 37, 38 are objected for reasons discussed below.

Claims 1, 11, 12, 36 and 41 are rejected under 35 U.S.C. 102(b) for reasons discussed below.

Claims 9, 10, 35, 39, 40 and 42 are rejected under 35 U.S.C. 112 2nd paragraph for reasons below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 10-12, 33 and newly added claims 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that unlike *Regents of the University of California v. Eli Lilly & Co. case*, the present specification does not merely include a statement that fragments of the isolated nucleotide sequence obtained from 5' sequence of murine villin gene are included in the invention, but describes fragments of the murine villin promoter. Applicants assert that the structural properties are defined in the present specification. Applicants further assert that the function of the fragments is also described as "having cis-regulatory activity that promotes transcription and tissue specific expression of the murine villin gene." Applicants thus conclude that the written description requirement is met.

These arguments have been fully considered but deemed unpersuasive. As discussed in the previous office action, the claimed 9kb fragment and fragments within is not limited to the 9kb fragment having the sequence of SEQ ID NO:1. It includes any 9kb fragment or fragments within as long as it is 5' to the murine villin gene. The function of the "having cis-regulatory activity that promotes transcription and tissue specific expression of the murine villin gene" merely points to any promoter activity that direct to a tissue specific expression (regardless what kind of tissue or whether it is specific to the endogenous villin gene expression). As such, the claimed genus is huge. The specification describes only one 9kb fragment having the sequence of SEQ ID NO:1

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and fragments within said fragments that directs tissue specific activity as the endogenous villin gene. This is not a representative species for all the 9kb fragments 5' to mouse villin gene. Therefore, the written description requirement is not met and the rejection is maintained.

Newly added claims 42 and 43 are rejected for same reasons as discussed previously and above. The HS I and HS IV DNase site is not limited to the sites within the SEQ ID NO:1, they would encompass any of sites that is upstream of the mouse villin gene.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11, 12, 36 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunbar et al (1997, see IDS).

Dunbar et al. disclose a 600 bp 5' fragment of the mouse villin gene. Dunbar et al. disclose that this fragment have promoter activity in vitro and directs expression of a reporter for tissue specific expression in mouse. Although the tissue specific expression is not same as the endogenous mouse villin gene, the claim limitation only recites "tissue specific expression" without specifying which tissue. Therefore, Dunbar et al. disclosed instantly claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9, 10, 35, 39, 40 and 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 9, 10, 35, 39 and 40, the recitation of “the region/fragment corresponding to intron 1” renders the claim indefinite because it is unclear whether it is directed to the intron 1 of the murine villin gene or other sequences that “corresponds” to intron 1 of the murine villin gene. Amending the claims to recite “the intron 1 region” may obviate this rejection.

Regarding claim 42, the recitation of “(i) a nucleotide...or” renders the claim indefinite because it is unclear whether the sentence is finished or it is limited to this nucleotide.

Allowable Subject Matter

Claims 3-6, 8, 37, 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER

